

DT02 Rec'd PCT/PTO

16 NOV 2004

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Ashley, Robert	Examiner:	Unassigned
Serial No.:	10/508,839	Group Art Unit:	Unassigned
Confirmation No:	Unassigned	Docket:	512-68 PCT/US
Filed:	September 21, 2004	Dated:	November 12, 2004
For:	Methods of Simultaneously Treating Mucositis and Fungal Infection		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

*I hereby certify this correspondence is being deposited  
with the United States Postal Service as first class mail,  
postpaid in an envelope, addressed to: Commissioner  
for Patents, P.O. Box 1450, Alexandria, Virginia  
22313-1450 on November 12, 2004*

Signed: Nicole R. Spore**INFORMATION DISCLOSURE STATEMENT**

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R.

§1.56, Applicant submits herewith the following Information Disclosure Statement in  
accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

**UNITED STATES PATENT PUBLICATIONS**

<b><u>INVENTOR</u></b>	<b><u>PUBLICATION NO.</u></b>	<b><u>PUBLICATION DATE</u></b>
Ashley	2003/0139380 A1	July 24, 2003
Nieman et al.	2004/0092491	May 13, 2004

**UNITED STATES PATENTS**

<b><u>PATENTEE</u></b>	<b><u>PATENT NO.</u></b>	<b><u>ISSUE DATE</u></b>
Martin et al.	4,957,918	September 18, 1990
Ritter	5,122,519	June 16, 1992
Van Wauwe et al.	5,157,046	October 20, 1992

McNamara et al.	5,223,248	June 29, 1993
Savage et al.	5,366,995	November 22, 1994
Golub et al.	5,532,227	July 2, 1996
McNamara et al.	5,770,588	June 23, 1998
Levy	5,811,412	September 22, 1998
Ramamurthy et al.	5,827,840	October 27, 1998
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Sum et al.	5,886,175	March 23, 1999
Gans	5,908,838	June 1, 1999
Ramamurthy et al.	5,998,390	December 7, 1999
Wiostko, Emil	6,015,803	January 18, 2000
Golub et al.	6,015,804	January 18, 2000
Ramamurthy et al.	6,114,316	September 5, 2000
Asculia et al.	6,159,955 A	December 12, 2000
Murad, Howard	6,296,880	October 2, 2001
Berman	6,384,081	May 7, 2002
Pflugfelder et al.	6,455,583	September 24, 2002
Buseman et al.	6,495,158	December 17, 2002
Avery et al.	6,664,287	December 16, 2003
Berman	RE 038386	January 13, 2004

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<b><u>COUNTRY</u></b>	<b><u>PUBLICATION NO.</u></b>	<b><u>PUBLICATION DATE</u></b>
Japan	JP 01006437 A (Abstract)	January 10, 1990
WO	99/37800	July 29, 1999
WO	99/37306	July 29, 1999
WO	99/58131	November 18, 1999
WO	00/07601	February 17, 2000

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1. Akamatsu, et al. "Effect of Keigai-Rengyo-To, a Japanese Kampo Medicine, on Neutrophil Functions: a Possible Mechanism of Action of Keigai-Rengyo-To in Acne," *The Journal of International Medical Research*, 25: 255-265 (1997).
2. Baer, et al. "High-Dose Tetracycline Therapy in Severe Acne," *Arch Dermatol*, 112:479-481 (April 1976).
3. Cheryl Guttman, "Emerging resistance changes face of antibiotic therapy for acne," *Dermatology Times*, January 2001, page 22.
4. Hirohiko Akamatsu, Maki Asada, Jinro Komura, Yasuo Asada, and Yukie Niwa, "Effect of Doxycycline on the Generation of Reactive Oxygen Species: A Possible Mechanism of Action of Acne Therapy with Doxycycline," *Acta Derm Venereol (Stockh)* 72:178-178 (1992).
5. Bodokh, Y. Jacomet, J. Ph. Lacour and J.P. Ortonne, "Minocycline Induces an Increase in the Number of Excreting Pilosebaceous Follicles in Acne Vulgaris," *Acta Derm Venereol (Stockh)*, 77:255-259 (1997).
6. W. J. Cunliffe, M.D., F.R.C.P., "Evolution of a Strategy for the Treatment of Acne," *J Am Acad Dermatol*, 16:591-9 (1987).
7. E. Anne Eady, Eileen Ingham, Christina E. Walters, Jonathan H. Cove, and William J. Cunliffe, "Modulation of Comedonal Levels of Interleukin-1 in Acne Patients Treated with Tetracyclines," *J. Invest Dermatol*, 101:86-91 (1993).
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10. Sainte-Marie, I. Tenaud, O. Jumbou and B. Dréno, "Minocycline Modulation of Alpha-MSH Production by Keratinocytes *In vitro*," *Acta Derm Venereol* 79:265-267 (1999).
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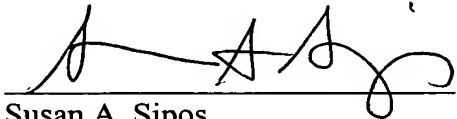
13. M. Toyoda and M. Morohashi, "An Overview of Topical Antibiotics for Acne Treatment," *Dermatology*, 196:130-134 (1998).
14. Sheila E. Unkles, and Curtis G. Gemmell, "Effect of Clindamycin, Erythromycin, Lincomycin, and Tetracycline on Growth and Extracellular Lipase Production by *Propionibacteria* In Vitro," *Antimicrobial Agents and Chemotherapy*, 21:39-43 (1982).
15. G.F. Webster, K.J. McGinley, and J.J. Leyden, "Inhibition of Lipase Production in *Propionibacterium acnes* by Sub-Minimal-Inhibitory Concentrations of Tetracycline and Erythromycin," *British Journal of Dermatology*, 104:453-457 (1981).
16. Guy F. Webster, M.D., Ph.D., Susan M. Toso, M.S., and Lutz Hegemann, M.D., Ph.D., "Inhibition of a Model of In Vitro Granuloma Formation by Tetracyclines and Ciprofloxacin," *Arch Dermatol.*, 130:748-752 (1994).
17. Reynold C. Wong, M.D., Sewon Kang, M.P.H., Jan L. Heezen, L.P.N., John J. Voorhees, M.D., and Charles N. Ellis, M.D., "Oral Ibuprofen and Tetracycline for the Treatment of Acne Vulgaris," *J Am Acad Dermatol*, 11:1076-1081 (1984).
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19. Bikowski, J.B., "Treatment of rosacea with doxycycline monohydrate," *Curtis*. 2000 Aug., 66(2):149-152.
20. Jimenez-Acosta, "Response to tetracycline of telangiectasias in male hemophiliac with human immunodeficiency virus infection," *J. Am. Acad. Dermatol.* 1988 Aug., 19(2 Pt. 1):369-379.
21. Torresani, C., "Clarithromycin versus doxycycline in the treatment of rosacea," *Int. J. Clin. Dermatol.* 1997 Dec., 36(12):942-946.
22. McClellan, K.J., "Topical Metronidazole. A review of its use in rosacea," *Am. J. Clin. Dermatol.* 2000 May-June, 1(3):191-199.
23. Quarterman, M.J., "Ocular Rosacea. Signs, symptoms and tear studies before and after treatment with doxycycline," *Arch. Dermatol.* 1997 Jan., 133(1):49-54.
24. Dursun D. et al. "Treatment of recalcitrant recurrent corneal erosions with inhibitors of matrix metalloproteinase-9, doxycycline and corticosteroids." *Am. J. Ophthalmol.*, 132(1):8-13 (July 2001).
25. Dursun D. et al. "Pseudokeratoconus caused by rosacea." *Cornea*, 20(6):668-9 (August 2001).

26. Li DQ, et al. "Regulation of MMP-9 production by human corneal epithelial cells." *Exp. Eye Res.*, 73(4):449-59 (October 2001).
27. Solomon A., et al. "Doxycycline inhibition of interleukin-1 in the corneal epithelium." *Invest. Ophthalmol Vis. Sci.*, 41(9):2544-57 (August 2000).
28. Sobrin L., et al. "Regulation of MMP-9 activity in human tear fluid and corneal epithelial culture supernatant." *Invest. Ophthalmol. Vis. Sci.*, 41(7):1703-9 (June 2000).
29. Gilbard JP., et al. "Dry eye, blepharitis and chronic eye irritation: divide and conquer." *J. Ophthalmic Nurs. Technology*, 18(3):109-15 (May-June 1999).
30. Freinkel et al. "Effect of tetracycline on the composition of sebum in acne vulgaris." *New England Journal of Medicine*, 1965, Vol. 273, No. 16, pages 850-854, (abstract only).
31. Database CA Online! Chemical Abstracts Service, Columbus, Ohio, US; Pruzanski, Waldemar, et al., "Chemically modified non-antimicrobial tetracyclines inhibit activity of phospholipases A2", STN Database Accession No. 130:20186 XP002246102 (Abstract).
32. Liu, Yu, et al., "A chemically modified tetracycline (CMT-3) is a new antifungal agent", *Antimicrobial Agents and Chemotherapy*, pp. 1447-1454 (2002).
33. Stedman's Medical Dictionary 27<sup>th</sup> Edition.
34. Wilkin, et al., "Standard classification of rosacea: Report of the National Rosacea Society Expert Committee on the Classification and Staging of Rosacea", *J Am Acad Dermatol*, pp. 584-587 (April 2002).

A copy of each reference cited above is enclosed. A separate listing of all the references has been set forth on the enclosed form PTO-1449. The Examiner is respectfully requested to consider these references in their entireties, and to indicate that he or she has done so by initialing the form PTO-1449.

In view of the present submission, it is believed that the above-referenced application is, in all respects, complete and in condition for further examination and favorable consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Susan A. Sipos', written over a horizontal line.

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 512-68 PCT/US	SERIAL NO. 10/508,839
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)	APPLICANT Ashley, Robert	CONFIRMATION NO. Unassigned
	FILING DATE September 21, 2004	GROUP Unassigned

## U.S. PATENT PUBLICATIONS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		2003/0139380 A1	7/24/03	Ashley			
		2004/0092491	5/13/04	Nieman et al.			

## U.S. PATENT DOCUMENTS

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		4,957,918	September 18, 1990	Martin et al.			
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		5,366,995	November 22, 1994	Savage et al.			
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		6,384,081	May 7, 2002	Berman			
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		6,495,158	December 17, 2002	Buseman et al.			
		6,664,287	December 16, 2003	Avery et al.			
		RE 038386	January 13, 2004	Berman			

## FOREIGN PATENT DOCUMENTS

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							YES	NO
		JP 01006437 A (Abstract)	January 10, 1990	Japan				
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Akamatsu, et al. "Effect of Keigai-Rengyo-To, a Japanese Kampo Medicine, on Neutrophil Functions: a Possible Mechanism of Action of Keigai-Rengyo-To in Acne," <i>The Journal of International Medical Research</i> , 25: 255-265 (1997).
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			Nancy B. Esterly, M.D., Nancy L. Furey, M.D., and Lillian E. Flanagan, B.S., "The Effect of Antimicrobial Agents on Leukocyte Chemotaxis," <i>The Journal of Investigative Dermatology</i> , 70(1):51-55 (1978).

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